EXHIBIT C

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Carol Ocker, et al. v. Ethicon, Inc.., et al No. 2:12-cv-00878	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Marc J. Bern and Partners Law Firm to give medical opinions related to Carol Ocker. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including autologous tissue based slings, biological graft-based

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slings, and periurethral bulking procedures. I have attended training provided by Ethicon, Inc. including training on TVT devices. Additionally, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following documents, medical records with accompanying exhibits pertaining to Carol Ocker:

River Hills Community Health Center;
- Monroe County Hospital and Clinics;
- Lakeview Surgery Center;
- Michael Shaeffer MD;
- The Iowa Clinic Ob Gyn;
- May Clinic;
- Sycamore Shoals Hospital;

I have also reviewed medical literature, relevant depositions, and other TVM related documents (enclosed separately as my reliance list) to assist in formulating my opinions.

Clinical History

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- On March 30th, 2005, Carol Ocker was a 48 year-old G3P2 patient referred to Dr. Eric Garner secondary to stress urinary incontinence (SUI). Medical therapy had failed. Her past medical history was remarkable in part for hypertension, [redacted] hot flashes, and a history of bunion surgery. Physical exam revealed a small cystocele, a small rectocele, and urethral hypermobility.

- On April 19th, 2005, Dr. Garner performed a retropubic TVT-sling placement. He memorializes that he placed the sling in a tension-free fashion, memorializing that "at the end of the procedure, the urethra was mobile still. There was no tension." A Foley catheter was placed during the procedure. She was discharged home later that day with a Foley catheter and was instructed to remove the catheter 2 days later.

- Between April 20th and 27th, 2005, Ms. Ocker suffered repeated bouts of urinary retention and had complaints of burning and irritation associated with the catheter. On April 27th, she was taught how to perform clean intermittent catheterization (CIC).

- On June 14th, 2005, Dr. Garner saw Ms. Ocker and noted that she had not been catheterizing over the preceding two weeks. Although her stream was slow,

- On August 11th, 2005, Dr. Garner and Ms. Ocker had a telephone conversation regarding the TVT procedure at which time she stated that "something is just not right".

- On September 6th, 2005, Ms. Ocker underwent a dilatation and curettage (D and C), performed by Dr. Vincent Sullivan secondary to abnormal vaginal and uterine bleeding with the pathological specimen revealing no atypia.

- On August 31st, 2009, she saw Wendy Wilgus, APN, with complaints of urgency incontinence and dysuria. She was empirically treated with Cipro and referred to Dr. Scott May.

- On September 1st, 2009, she saw Dr. Scott May with complaints of vaginal bulge and urinary incontinence. He memorializes that she had tried drugs such as Ditropan after her last surgery to no avail. Physical exam revealed a 3rd degree rectocele and a small cystocele.

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- On February 25th, 2010, she presented to Dr. May with complaints of urinary incontinence and dysuria. She had been previously treated with antibiotics for a UTI with resolution of her symptoms but subsequently developed dysuria and was started on Pyridium. Her physical exam was unchanged and she was prescribed Cipro. She was instructed to see Dr. Jones (Urology) and undergo urodynamics. She did see Dr. Jones on May 24th, 2010 and was prescribed Vesicare 5 mg daily.

- On October 15th, 2010, Ms. Ocker returned to see Dr. May in follow-up. Dr. Jones had seen her (as stated above) and felt her incontinence was related to urgency urinary incontinence. Medical therapy for this was unsuccessful. Her symptoms of vaginal bulge were unchanged. She was counselled to undergo rectocele repair.

- On December 6th, 2010, she underwent an uncomplicated rectocele repair by Dr. May.

- On January 3rd, 2011 she saw Dr. May for a post-operative visit recovering well from her posterior repair. She was noted to have minimal introital stenosis and was offered vaginal dilators.

- On January 21st, 2015, she saw Dr. Michael Shaeffer with complaints of mixed urinary incontinence (MUI) for 2-3 years with urgency, frequency, and nocturia x 4. She was found to have incomplete bladder emptying with a post-void residual (PVR) of 256 cc and prescribed Flomax.

- On February 5th, 2015, she saw Dr. Shaeffer with continued symptoms of MUI, unchanged on Flomax. Her PVR was 113 cc and she was increased on her Flomax to two capsules daily.

- On March 24th, 2015, she followed up with Dr. Shaeffer with continued complaints of MUI as well as malaise and lightheadness. She was found to have a UTI and was prescribed Cipro. Her PVR was now 34 cc. She was switched from Flomax to Uroxatral to offset Flomax-related side effects.

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- On April 15th, 2015, she returned to Dr. Shaeffer with continued MUI symptoms. She was unable to tolerate Uroxatral and was switched to Rapaflo.

- On May 8th, 2015, she saw Dr. Shaeffer with non-progressive symptoms on Rapaflo. Her PVR was 65 cc and she was started on Vesicare 2.5 mg daily.

- On May 27th, 2015, she saw Dr. Shaeffer with continued non-progressive symptoms. Her PVR was 23 cc. She was diagnosed with another UTI.

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

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It is my opinion the IFU for the TVT in 2005 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues.

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Moreover, in all of my experiences removing mesh, residual scarring of the vagina, peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2005 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2005, alternative successful and safer sling procedures were available, including biologic and autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Ms. Ocker was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia. As such, Dr. Garner was unable to warn Ms. Ocker of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Ms. Ocker suffered vaginal sling contraction as a result of the physical properties of the TVT device. These conditions are clinically reflected in the voiding dysfunction clinically documented in the medical records.

A. Contraction/Shrinkage

Ms. Ocker's TVT contracted post implantation. Although she had transient obstruction for 6 weeks following her procedure (requiring CIC), she then returned to a normal voiding pattern over the next four years. She then developed voiding dysfunction in the form of mixed urinary incontinence (MUI) with a primary

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component of urinary urgency. She also started developing recurrent incomplete bladder emptying symptoms, well documented in the records of Dr. Shaeffer.

I have observed "taut" pieces of transvaginal mesh in my clinical practice that is the result of post-implantation contraction or shrinkage of the mesh. The post-implantation shrinkage of the mesh involves a combination of two factors: one being the mesh itself contracting and the other being the foreign body response generating a fibrotic response that entails wound contracture.

Case Specific Opinion No. 2

Ms. Ockers's vaginal pain and dyspareunia was caused by contraction of the TVT device. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury; (7) lichen sclerosis; (8) vaginal tissue atrophy; and (8) pelvic floor dysfunction. [1]

I am able to exclude mesh erosion, paraurethral banding, and inflammation as causes of Ms. Ocker's dyspareunia and vaginal pain because there is no documentation of these conditions in the medical records

I am able to rule in contraction as a likely cause of Ms. Ocker's vaginal pain and dyspareunia. These conditions are documented in the medical records of Drs. May, Jones, and Shaeffer and further elaborated upon in Ms. Ocker's deposition. As previously stated in Case Specific Opinion No.1, Ms. Ocker's voiding dysfunction developed as a result of mesh contraction. This mesh contraction also contributed to her dyspareunia.

I am able include scarring with reduced elasticity as a cause of Ms. Ocker's dyspareunia and pelvic pain. Mesh contraction typically occurs with wound contracture; although the medical records I've reviewed do not clearly identify this finding, mesh contraction typically occurs in concert with local scarring as the mesh

[1] (Ashok, 2012)

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creates a foreign body response which entails chronic inflammation, fibrosis, and scar formation.

I am able to exclude neuromuscular injury, lichen sclerosis, and pelvic floor dysfunction as causes of Ms. Ocker's dyspareunia and vaginal pain because there is no documentation of these conditions in the medical records

Vaginal tissue atrophy is excludable as the cause of Ms. Ocker's pelvic pain and dyspareunia not only because she was likely pre-menopausal at the time of surgery but also because she had multiple pelvic exams post-operatively, none of which documented this finding.

Case Specific Opinion No. 3

Ms. Ocker continues to have pelvic pain, dyspareunia and voiding dysfunction presently. She has voiding dysfunction most likely secondary to pelvic floor scarring in the context of mesh contraction and foreign body response to mesh. As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elastic and compliance of these tissues. As such, when patients present with complications from synthetic mesh slings, they tend to develop a combination of incomplete emptying in addition to urinary incontinence that is often both stress incontinence in combination with urgency urinary incontinence. This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis. Overactive bladder (OAB) medications such as Vesicare are contraindicated in these patients because they tend to worsen their ability to empty their bladders.

Case Specific Opinion No. 4

Ms. Ocker's future prognosis as it relates to her pelvic pain, dyspareunia, and voiding dysfunction is guarded. Because she has residual pelvic mesh still inside of

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her body, she will continue to suffer from pelvic pain and dyspareunia. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure.

In as much an autologous fascial sling or other procedures (not involving synthetic mesh) for incontinence might be considered, these would be inappropriate at the current time in the presence of her mesh sling. Additionally, autologous fascial slings are contraindicated in patients with elevated post-void residuals because they are likely to worsen this condition or even create urinary retention. For this reason, Ms. Ocker currently is not a candidate for this type of surgery and is best treated with medical therapy in combination with lifestyle modifications and pelvic floor physiotherapy. Although these interventions should be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, pelvic pain, and dyspareunia will be a lifelong condition for this patient. Moreover, alternative successful and safer sling procedures were available at the time of her original synthetic mesh sling implantation, including the use of a biologic sling or an autologous fascial sling. These safer alternative sling procedures would not have resulted in the same symptoms and injuries that Ms. Ocker now suffers.

These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.

Sincerely,

Konstantin Walmsley, M.D.

1/17/17